IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA SOUTHERN DIVISION No. 7:23-CV-897

IN RE:

CAMP LEJEUNE WATER LITIGATION

This Document Relates To:

McElhiney v. United States, 7:23-cv-1368 Peterson v. United States, 7:23-cv-1576 Rothchild v. United States, 7:23-cv-858 Sparks v. United States, 7:23-cv-682 Welch v. United States, 7:23-cv-1503 UNITED STATES' REPLY MEMORANDUM
OF LAW IN SUPPORT OF ITS MOTION TO
EXCLUDE PLAINTIFFS' PARKINSON'S
DISEASE EXPERTS DRS. STEVEN BIRD,
JASON CANNON, AMELIA BOEHME,
GARY MILLER, BRIANA DE MIRANDA,
LUCIO COSTA, AND MICHAEL
FREEMAN

("Unreliable PD Literature Reviews")

INTRODUCTION

Plaintiffs' Opposition suggests that the requirements of Federal Rule of Evidence 702 are optional and asks the Court to exercise lenience and excuse their experts' unreliable literature reviews. In support, Plaintiffs overcomplicate the role of the Court in determining admissibility under Rule 702 and oversimplify what is required by experts under the Rule. Plaintiffs additionally try to justify why certain studies were omitted by their experts. See D.E. 694 at 18 n.9. Contrary to Plaintiffs' argument, the Court need not weigh the evidence to make a Rule 702 decision on whether Plaintiffs' experts employed unreliable methods and cherry-picked studies. It need only look at their inadequate search methodology and the amount of relevant information they failed to consider.

Given that Plaintiffs' experts' literature reviews fall woefully short of Rule 702's reliability standards, the Court should exclude the expert opinion testimony of Dr. Steven Bird, Dr. Gary Miller, Dr. Jason Cannon, Dr. Amelia Boehme, Dr. Briana De Miranda, Dr. Lucio Costa, and Dr. Michael Freeman in its entirety. ¹

ARGUMENT

I. Plaintiffs' Experts Failed to Employ a Reliable Literature Review Methodology.

Plaintiffs argue that the United States created "its own unreasonable [ness] standard" for a reliable literature review. D.E. 694 at 8. However, that is simply not the case. As Plaintiffs acknowledge in their Opposition, "a reliable literature review 'uses formal search methods to allow a researcher to obtain a neutral snapshot of the existing research on a particular question." *Id.* at 4 (quoting *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 929 (D.S.C. 2016) (internal citation omitted)). Plaintiffs' experts failed to meet this standard; their literature reviews were neither "transparent" nor "reproducible." *See* D.E. 542 at 17–36; *see also In re Lipitor*, 174 F. Supp. 3d at

¹ The United States disagrees that the request in its initial motion was "unclear." However, the United States reiterates that it requests that the opinions of Drs. Steven Bird, Jason Cannon, Amelia Boehme, Gary Miller, Briana De Miranda, Lucio Costa, and Michael Freeman (collectively "Plaintiffs' experts") should be excluded in their entirety because their literature reviews are unreliable for a variety of reasons as explained in the United States' memorandum of law in support of its motion and here. *See generally* D.E. <u>542</u>.

929. Furthermore, either the experts' unreliable methods resulted in a failure to capture relevant studies or the experts intentionally failed to account for relevant studies in reaching their conclusions. Either way, Plaintiffs' experts' methods fail to pass muster under Rule 702.

A literature review should be "transparent" and "reproducible" in order to show that the expert "obtain[ed] a complete view of the literature, rather than cherry-picking articles based on the [expert's] biases." *In re Lipitor*, 174 F. Supp. 3d at 929. As Plaintiffs underscore, their experts' search terms were neither transparent nor reproducible. For example, Plaintiffs explain that Dr. Bird used "relevant keywords, such as 'TCE' and 'Parkinson's Disease." D.E. 694 at 6. This begs the question of what other keywords Dr. Bird deemed relevant to include in his search and what exclusion or inclusion criteria Dr. Bird employed. The sheer number of scientific studies reviewed by each expert further highlights differences in each expert's review as Dr. Bird reviewed 184 scientific studies, yet Dr. Costa only reviewed 57. *Id.* at 4. Such discrepancies cannot be fully understood because the experts failed to provide a complete and transparent explanation of their review methods.

Contrary to Plaintiffs' argument, an analysis of which studies an expert considered goes to admissibility and not weight; it is relevant to whether the expert's "testimony is based on sufficient facts or data" and whether "the expert's opinion reflects a reliable application of principles and methods to the facts of the case." Fed. R. Evid. 702(b), 702(d). The Advisory Committee confirmed that questions about the sufficiency of the basis for an expert's opinion and application of the expert's methodology are questions of admissibility, not weight. Fed. R. Evid 702 advisory committee's note to the 2023 amendments (noting that admissibility questions are to be decided as preliminary matters under Fed. R. Evid. 104(a) rather than deferred under 104(b)). Therefore, a "[c]ourt must find more than [a] 'hypothesis and speculation,'" as the methodology [] used in forming a conclusion based upon [a] review of literature." *Doe v. Ortho-Clinical Diagnostics, Inc.* 440 F. Supp. 2d 465, 474 (M.D.N.C. 2006).

² TCE is an abbreviation of tetrachloroethylene.

The United States' challenge to the extreme cherry-picking of Plaintiffs' experts is an evidentiary admissibility challenge that should be decided as a preliminary matter and not deferred. A "[r]esult-driven analysis, or cherry-picking, undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion." *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II)* MDL 2502, 892 F.3d 624, 634 (4th Cir. 2018). Thus, it is a matter of admissibility. *See id.; see also EEOC v. Freeman*, 778 F.3d 463, 469–70 (4th Cir. 2015) (Agee, J., concurring) (collecting cases and noting that "courts have consistently excluded expert testimony that 'cherry-picks' relevant data").

Moreover, to determine admissibility here, the Court does not need to "become scientific experts" as Plaintiffs claim. D.E. <u>694</u> at 17 (quoting *United States v. Day*, 524 F.3d 1361, 1368 (D.C. Cir 2008) (citation omitted)). As Plaintiffs themselves agree, the literature at issue for Parkinson's disease is a relatively small number of studies, which makes the experts' cherry-picking readily apparent. *See id.* (describing the United States as alleging that Plaintiffs' experts failed to review a small number of studies); *see also In re Paraquat Prods. Liab. Litig.*, 730 F. Supp. 3d 793, 807 (S.D. Ill. 2024) ("total immersion" into scientific disciplines are "neither required, nor possible," but a "high-level discussion of relevant scientific concepts and methodologies is appropriate to provide the analytical framework for the court's admissibility analysis"). Indeed, courts frequently undertake such analyses into whether experts appropriately considered relevant studies, as evidenced by the body of case law on expert cherry-picking. *See, e.g., In re Lipitor,* 174 F. Supp. 3d at 930; *In re Paraquat Prods. Liab. Litig.,* 730 F. Supp. at 807.

II. Plaintiffs' Experts Used Unreliable and Unreproducible Methods in Performing Their Literature Reviews.

Despite Plaintiffs' arguments to the contrary, a failure to consider studies that run contrary to an expert's conclusions is a clear instance of the expert failing to apply the same level of analysis that the expert would follow outside of the courtroom. Cherry-picking supportive results without accounting for contrary evidence renders the results of such an expert's analysis categorically inadmissible under Rule 702. *See McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 1005 (4th Cir. 2020) (Agee, J., concurring in part)

(quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)) (for an expert's opinion to be admissible, the experts must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); Fed. R. Civ. P. 702 commentary to the 2000 amendments (among factors found relevant in determining whether expert testimony is sufficiently reliable include "[w]hether the expert 'is being as careful as he would be in his regular professional work outside his paid litigation consulting" (quoting *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997)). This is precisely what Plaintiffs' experts impermissibly did here.

For example, Plaintiffs do not contest that in Dr. Bird's literature reviews outside of the courtroom, he uses the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist" and identifies the numbers of studies included or excluded (along with the reasons for exclusion). *See* D.E. 694, 7, n.3. Such methodological rigors are conspicuously absent from Dr. Bird's litigation work here. Dr. Bird is unable to provide (1) a complete list of his search terms, *see* Bird GC Dep. Tr. at 235:22–237:7 (JA Ex. 148, D.E. 469-2); (2) the number of studies returned as a result of his searches, *id.* at 88:1–7; or (3) the criteria he used for including or excluding a study in his overall consideration, *id.* at 89:12–17 (exclusion criteria); 90:4–9 (no record of which studies were included or excluded). Indeed, Dr. David Savitz, one of Plaintiffs' epidemiology experts advocated for a much higher standard for literature reviews, including "gathering all the relevant peer-reviewed literature on the question," and "examin[ing] [the studies] and organ[izing] them based on their methods." *See* D.E. 542 at 18 (quoting Savitz 3d Dep. Tr. at 29:18–24; 159:24–165:25; (JA Ex. 154, D.E. 469-8)).

Similarly, Plaintiffs' only justification for the deficiencies in Dr. Freeman's methodology is to point to the United States' motion to exclude certain experts' *kidney cancer* opinions, *see* D. E. <u>694</u> at 26–27 (citing D.E. <u>575</u> at 5), where the United States recognized that Dr. Freeman "acknowledged a wider range of studies that do not support his opinions[,]" United States Mem. Supp. Mot. "Kidney Cancer Lit. Review," D.E. <u>575</u>, at 17. However, the issues the United States raised in its initial motion for Parkinson's disease are different. For Parkinson's disease, unlike for kidney cancer, Dr. Freeman did not provide the search terms that he used, did not identify the databases that he searched, and did not verify that he reviewed the

work of his staff member, Dr. Teeter, who excluded certain studies for Dr. Freeman's analysis of Parkinson's disease. *See* D.E. <u>542</u> at 8–9. In their Opposition, Plaintiffs do not justify or explain any of this and seemingly ignore that Parkinson's disease and kidney cancer are different diseases with different expert reports and different relevant studies. *See* D.E. <u>694</u> at 26–27.

A. The Plaintiffs' Experts Failed to Account for Highly Relevant Contrary Studies.

Rule 702 requires that expert opinion testimony only be admitted if the proponent demonstrates to the court that the testimony is helpful and reliable. *See* Fed. R. Evid. 702; advisory committee's note to 2023 amendment. Notwithstanding Plaintiffs' assertions to the contrary, their experts' literature reviews cannot be "neutral snapshots" when they omit only the studies that undermine their opinions. *See* Costa Dep. at 259:10–21 (JA Ex. 169, D.E. <u>470-8</u>) ("The papers that I reviewed for writing the report all go[in] the same direction [T]he only study that doesn't go in the same direction is the one I was not aware of, this – this Sallmén study, which didn't find any association with [trichloroethylene] or so."). Whether the failure to account for contrary studies was by design or through negligence is irrelevant under Rule 702 because the failure shows the unreliability of the expert's methodology and resulting opinion.

While Plaintiffs cite the statement in *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 858 (E.D.N.C. 2015), that "[a]n expert needs to 'acknowledge' and 'account' for evidence contrary to their opinion," they argue that an expert need not "cite and analyze all or even most of the hundreds of studies that exist." D.E. 694 at 11. Even if this is true, that does not excuse experts from accounting for highly relevant literature, such as Sallmén 2024, D.E 542-6, Silver 2014, D.E. 542-5, and the National Research Council's Report, NRC 2009 Report (JA Ex. 205, D.E. 476-3), each of which runs contrary to their opinions. The failure of Plaintiffs' experts to account for this literature is evidence of an unreliable methodology. Plaintiffs' dismissal of these studies in their Opposition, *see* D.E. 694 at 18–19, is unavailing because Rule 702 requires experts, not their attorneys, to explain why relevant studies were not included, or given less weight.

³ Notably, Plaintiffs do not offer examples of where the experts "review and engage with studies contrary to their conclusions" within any of the experts' reports. *See* D.E. <u>694</u> at 13.

See generally, Ziegler v. Polaris Indus., Inc., No. 1:23-CV-00112-MR-WCM, 2024 WL 482212, at *9 (W.D.N.C. Feb. 7, 2024) (excluding the testimony of an expert who "never explain[ed] how he applied" his methods).

In particular, Plaintiffs' justifications for not reviewing Sallmén 2024 are not persuasive. Their opposition states: "the most likely reason" their experts did not review the study was they "had yet to review the study which was published earlier that year." D.E. 694 at 18 n.9. Sallmén 2024 was published in January 2024, and therefore, Plaintiffs' experts had almost an entire year to find and review the study before their reports were due. Some of the experts also testified that they were aware of Sallmén 2024 but still did not include it in their reports. See Boehme Dep. Tr. 270:1–271:7 (JA Ex. 167, D.E. 470-6); De Miranda Dep. Tr. 37:25-38:2; 41:4-7; 226:1-7 (JA Ex. 167, D.E. 470-6). Plaintiffs' further attempt to explain their experts' omission by explaining that it is "unsurprising the article was not immediately identified" because of the limited appearance of the terms "PCE," and "trichloroethylene" in the study. D.E. 694 at 18 n.9. However, "chlorinated solvents" is in the title of the study and that was one of the "primary search terms" Dr. Cannon claimed he used. As another example, Dr. Boehme used the search term "occupational exposures and Parkinson's disease," D.E. 542-2, Letter from Leslie LaMacchia to Sara Mirsky (May 30, 2025), and the study is called "Parkinson's disease and occupational exposure to organic solvents," Sallmén 2024, D.E. 542-7. It is therefore unconvincing that the study would not have come up in the experts' searches. Moreover, Sallmén is plainly relevant to Plaintiffs' experts' opinions and if it was not generated in their literature searches, this is only further evidence that their literature reviews were inadequate.

III. <u>Plaintiffs' Experts Cannot Rely on an Agency Review to Cure the Flaws in Their Methodologies.</u>

Plaintiffs cite *Lightfoot v. Georgia-Pacific* and claim it is dispositive on the reliability of Plaintiffs' experts' literature reviews. D.E. <u>694</u> at 14–16 (*Lightfoot v. Georgia-Pac. Wood Prods., LLC* No. 7:16-CV-244-FL, 2018 WL 4517616, at *11 (E.D.N.C. Sept. 20, 2018), order amended on reconsideration, No. 7:16-

⁴ PCE is an abbreviation of perchloroethylene.

CV-244-FL, 2018 WL 67296). In *Lightfoot*, the Court held that an expert's review of an agency monograph and "a wide range of studies" selected *without* "cherry-pick[ing]" was sufficiently reliable under *Daubert*. *Lightfoot*, 2018 WL 4517616, at *11 (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)). Therefore, *Lightfoot* does not stand for the proposition that reliance on agency review alone is sufficient, when there are contrary studies that are not accounted for by the agency's review.

In this case, relying on an agency's review as a substitute for a proper literature review does not constitute a reliable methodology. For one thing, the Agency for Toxic Substances and Disease Registry's ("ATSDR") Assessment of Evidence that Plaintiffs' experts cite did not account for Sallmén 2024, which was published several years after the ATSDR's review. None of the experts then considered Sallmén 2024 to fill the hole left by the Assessment of Evidence, which was published in 2017. Further, the Assessment of the Evidence does not itself establish general causation, but is a policy-based document. 5 See Yates v. Ford Motor Co., No. 5:12-cv-752-FL, 2015 WL 2189774, *23 (E.D.N.C. May 11, 2015) ("Courts have indeed recognized a distinction between the assessments of regulatory agencies and the standard of medical causation necessary for tort liability."); see also id. at *23 n.7 (collecting cases). And, to the extent that Plaintiffs' experts relied on the Assessment of the Evidence, it does not absolve them of having to review any outside or subsequently published literature. Taking an uncritical view of an agency review is not helpful to the Court; otherwise, the Court need not look past the agency review at all, and expert testimony would be unnecessary. Nix v. Chemours Co. FC, LLC, No. 7:17-CV-189-D, F. Supp. 3d , 2025 WL 2924613, at *18 (E.D.N.C. Sep. 30, 2025) ("Nix II") (exclusion appropriate if expert only reads and reports on studies and has not "engaged with the relevant literature enough to assess whether a study is credible, to explain why they relied on one study more than another, and to articulate how they reached their conclusion in the face of conflicting evidence"); see also In re Camp Lejeune Water Litig., 736 F. Supp. 3d

⁵ Dr. Frank Bove was the sole author of the Assessment of the Evidence and drafted it by himself in six weeks. *See* D.E. <u>540</u> at 13 (discussing the policy-based nature of the 2017 Assessment).

311, 319 (E.D.N.C. 2024) (applying common-law tortprinciples to this case, including establishing specific and general causation through expert testimony).

IV. Dr. Cannon's Methodology is Neither Transparent Nor Reproducible.

Plaintiffs' Opposition does not address Dr. Cannon's faulty methodology, instead only asserting that his conclusions are correct. But Dr. Cannon engaged in quintessential cherry-picking by only including toxicological studies that supported his analogy of TCE to PCE and ignored the rest. ⁷ *Freeman*, 778 F.3d at 469–70 (Agee, J. concurring) ("cherry-picking data produces a misleadingly favorable result by looking only to 'good' outcomes.").

Dr. Cannon stated that "[r]esearch has shown that PCE and TCE act similarly in living systems," Cannon Rep. at 23 (JA Ex. 123, D.E. 467-6). But Dr. Cannon failed to cite Luo 2018, *see id.*, which states "There are differences in toxic effects of TCE and PCE in liver, kidney and other tissues," D.E. 542-13 at 2. Dr. Cannon fails to account for this contrary evidence in his report. At deposition, he testified that he "probably read [Luo 2018] at some point," Cannon Dep. Tr. 251:21–25 (JA Ex. 168, D.E. 470-7), but he could not explain the reason that the paper did not come up in the search terms that he claimed were the basis of his literature review, *see* Cannon Rep. at 3 (JA Ex. 123, D.E. 467-6). Dr. Cannon considered similar organ systems and animal studies, *see*, *e.g.*, *id.* at 18 (citing studies that reported associations between TCE exposure and PD-related phenotypes in animals), but because his exclusion criteria are unknown, there is no way to determine why he disregarded Luo 2018, *see In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig.* (No. 11), 341 F. Supp. 3d 213, 296 (S.D.N.Y. 2018) (inquiry is "whether [an expert] looked holistically or only selectively, at [the] body of evidence"), *aff'd* 982 F.3d 113 (2d Cir. 2020). The example

⁶ Plaintiffs, in passing, also reference the comprehensive efforts of "EPA, the NTP, and IARC." D.E. <u>694</u> at 15. However, it is unclear what efforts Plaintiffs are implying their experts relied on from that list. For instance, "IARC" stands for the International Agency for Research on Cancer. As PD is not a cancer, it is not surprising that none of Plaintiffs' experts relied on an IARC review. Accordingly, such efforts by IARC, which were neither relevant nor reviewed by Plaintiffs' experts, could not fill the holes left in their unreliable literature reviews.

⁷ The United States addresses the reliability and admissibility of Plaintiff' experts' opinions on PCE in a separate motion, D.E. <u>545</u>.

of Luo 2018 shows that Dr. Cannon's search methodology is neither transparent nor reproducible and only includes studies that support his view.

V. Dr. Boehme Disclaimed Expertise in the Toxicological Studies She Cited.

Plaintiffs' arguments regarding the reliability of Dr. Boehme's opinions on toxicology and neurotoxicology miss the point of the United States' challenge. Had Dr. Boehme assessed herself competent to testify about the biological mechanism of Parkinson's disease and TCE or PCE, the United States would not challenge her qualifications to testify about toxicological studies. However, Dr. Boehme refused to testify about such biological mechanisms each time the issue of mechanism of action was raised. She stated:

Q. So do you have any – would you say that you have any opinions regarding the toxicological opinions discussed in this section?

A. I am not --

[Plaintiffs' attorney]: Object to the – object to the form. Foundation.

A. I am not a toxicologist.

Boehme Dep. Tr. at 127:8-14 (JA Ex. 167, D.E. <u>470-6</u>). Expecting Dr. Boehme to be able to articulate an opinion on the toxicological studies that underpin an entire section of her report is hardly "tak[ing] advantage" of Dr. Boehme's admissions that she is not qualified to offer opinions on toxicology and neurotoxicology. *See* D.E. <u>694</u> at 24; *see also In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, No. 22MC3043 (DLC), 2024 WL 3357608, at *18 (S.D.N.Y. July 10, 2024) (excluding opinions of an epidemiologist because, *inter alia*, she could not "answer questions [about her opinions] without reading from her report, or provide even a 'high-level overview' of her proposed biological mechanism for [the disease at issue's] development"); *see also See Nix II*, __ F. Supp. 3d __ at *18. The United States' position is not, as Plaintiffs erroneously assert, that no epidemiologist can opine on biological plausibility or mechanism of action, but rather that an expert who includes studies in her report on these topics should be able to answer questions about them. This was not the case for Dr. Boheme:

Q: So in your opinion, the existence of the studies that are cited in your report is sufficient to support biological plausibility?

A: Again, I'm not going to speak on the mechanism of action

Q: But as you testified, you haven't analyzed the actual findings of the studies cited in your report?

A: For the mechanism of action, because that is not my expertise.

Boehme Dep. Tr. at 155:6–157:2 (JA Ex. 167, D.E. <u>470-6</u>). Dr. Boehme repeatedly testified that she was not qualified to opine on toxicological matters and therefore her testimony on such topics should be excluded. *See, e.g., Zellers v. NexTech Ne., LLC*, 533 F. App'x 192, 198–99 (4th Cir. 2013) (affirming exclusion of toxicologist's opinions regarding toxicity of certain chemicals because the expert had no training in the toxicity of the chemicals at issue); *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 392 (D. Md. 2001) ("[A]n expert who is a mechanical engineer is not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering"); *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799-800 (4th Cir. 1989) (witness with an M.B.A. was not qualified to opine on antitrust matters where there was "no indication" of "*any* training in the area of antitrust or credit"). This case is no different and the Court should not accept Plaintiffs' alarmist argument.

CONCLUSION

For the reasons stated herein and in the United States' Motion to Exclude Plaintiffs' Parkinson's Disease Experts, D.E. <u>542</u>, the United States respectfully requests that this Court exclude the testimony of Drs. Steven Bird, Jason Cannon, Amelia Boehme, Gary Miller, Briana De Miranda, Lucio Costa, and Michael Freeman.

Dated: December 12, 2025 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 12, 2025 I electronically filed the foregoing using the Court's Case Management/Electronic Case Files system, which will send notice to all counsel of record.

/s/ Anna Ellison

ANNA ELLISON